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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,363	05/25/2001	Dirk M. Anderson	2852-E	4679

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IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE, WA 98101

EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,363

Applicant(s)

ANDERSON ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-38 and 42-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-38 and 42-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 36-38 and 42-52 are pending in the instant application. Claims 38 and 42 have been amended and claims 50-52 have been added as requested by Applicant in Paper Number 13, filed July 14, 2003.

All claims are currently under examination.

Objection to Specification

2. The amendment filed July 14, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the intended use of the antibody compositions. Applicant is required to cancel the new matter in the reply to this Office Action. This objection would be withdrawn if the new sentence added to the paragraph were replaced with:

Also provided herein are compositions comprising antibodies to RANKL.

Withdrawn Claim Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 36, 37 and 42-49 remain rejected and new claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36, 37 and 42-52 are indefinite because claims 36 and 42 encompass an antibody that **specifically binds** to the RANKL polypeptide of SEQ ID NO: 13, and claim 38 encompasses a method for preparing an antibody that **binds** to the RANKL polypeptide of SEQ ID NO: 13. It is acknowledged that Applicants had amended claim 36 to “specifically binds”, and have explained what “specifically binds” would mean to one of ordinary skill in the art on pages 6-7 of the response, but because claim 38 was also amended to include “an antibody that binds”, it is not clear what the difference in scope between “binds” and “specifically binds” is. This rejection would be overcome if claims 38 and 50 were amended to recite an antibody that specifically binds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 36, 37 and 42-49 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al., U.S. Patent No. 6,242,586, for reasons of record in the previous office action, Paper No. 12, at pages 4-5, and below.

Applicants traverse the rejection on page 8 of the response and submit that the antibodies of Gorman et al. and the antibodies covered by the claims as amended are not the same, and that the 84% amino acid homology between the mouse and human proteins does not ensure cross-reactivity. Applicants submit that since Gorman et al. fails to disclose human RANKL sequences, it does not teach how to make antibodies that meet the limitations of the present claims, which cover only antibodies that specifically bind human RANKL, and that antibodies raised to mouse RANKL would not be expected to bind *specifically* to human RANKL. Applicants further submit that one relying on Gorman et al. would not be able to identify antibodies that specifically bind human RANKL because this reference does not disclose human RANKL sequences, and accordingly, Gorman et al. does not anticipate the antibodies described in claims 36, 37 and 42-49.

Applicants' arguments have been fully considered but are not deemed persuasive. Applicants on pages 6-8 discuss the term "specifically binds", and presents as Exhibit B page 332 of the William E. Paul Textbook "Fundamental Immunology", which discusses the specificity of an antibody, which "is defined by its ability to discriminate between the antigen against which it is made (called the homologous antigen, or immunogen) and any other antigen one might test." Although Gorman et al. do not disclose the human RANKL sequence, due to the high degree of homology between the two proteins, one of ordinary skill in the art would expect that many of the antibodies raised against the mouse RANKL protein would bind with

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high specificity (high affinity) to the human RANKL protein, and this term does not distinguish over the mouse antibodies. Therefore, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in black ink, reading "Lorraine Spector". The signature is written in a cursive, flowing style with a large loop at the end.

**LORRAINE SPECTOR
PRIMARY EXAMINER**